OIR Registration Form for Human Induced Pluripotent Stem Cells (iPSCs)

(formerly iPSC Checklist)

To be used for the acquisition, derivation or registration of iPSCs for Research in a NIH Intramural Research Program Laboratory

Date: _____

Please check one of the following:

____ Registration of cells derived or to be derived in my IRP lab

____ Request to acquire human induced Pluripotent Stem (iPS) cells for research in my laboratory from *(1) sources outside the NIH*

Section 1 – Information about Investigator and iPSC line

- Name:_____
- Institute/Center:_____
- Cell line name:_____
- Cell/tissue origin of cell used to make the iPS cell:_____
- Indicate the disease, if applicable:_____
- List any known genetic markers:_____
- Primary contact for these cells: _____
  Phone:_____Email:_____
- Secondary contact: _____
  Phone:_____Email:_____
- ***If the iPS cells were derived in your lab***
  - Did the cells/tissues come from a NIH repository? If so, please identify source_____
- ***If the iPS cells were not derived in your lab –***
  - Name and institution of the provider_____
    _____
  - Please provide a copy of the agreement from your TDC which was used or will be used to obtain the cells.
  - Please describe the mechanism that will be used to obtain the cells_____

- *If you are obtaining the cells from a foreign country:*
  - I am acquiring cells from a foreign country, and therefore have paid the required fees and completed the following shipping forms:
    _____USDA **16-3** Permits to Import or Transport Controlled Material or Organisms or Vectors
    _____USDA **16-7** Application for Permit to Import Cell Cultures and Their Products
    _____CDC Application for Permit for Import or Transport of Agents or Vectors of Human Disease (Document #101000--sent to NIH Quarantine Permit Service Office Bldg. 13, Rm. 3KO4; 301-496-2960 (Application does NOT go to CDC – NIH provides a courtesy letter for customs clearance).

Section 2 – Research project details

- Project Title:_____
- Proposed Research:_____

_____

_____

_____

_____

Section 3 – Human Subjects Research

- ***If the iPS cells were derived in your lab***
  v. If cells come from participants in clinical research with known identities, IRB must review and approve the protocol and consent form
    - Name of IRB_____
    - IRB number _____ Approval Date_____

- ***If the iPS cells were not derived in your lab or were derived from deidentified cells/materials in your lab –***
  □ Cell provider will not provide NIH with any information that allows linkage of the cells to their donors

□ Information will be provided to you that allows linkage of the cells to their donors _____. If so, IRB review and approval is required.

- Name of IRB_____
- IRB number _____ Approval Date_____

Section 4 – Institutional Biosafety Review

- *Institutional Biosafety Review is required when:*
  - iPS cells made by recombinant techniques (commercially or by another institution) are received by an NIH investigator for further study or use in animals.
  - iPS cells from human samples are received by an NIH investigator for further study or use in animals (regardless of derivation method).

For questions contact Richard Baumann, Institutional Biosafety Officer, 301-496-2960

- **IBC registration number** _____ date _____.

Section 5 – Research Requirements (Investigator must initial)

_____ I understand that when this checklist is completed and all approvals have been obtained, I am required to submit it to my TDC to obtain a material transfer agreement (MTA) with the provider, if the provider is not an NIH intramural laboratory. A list of TDCs for NIH can be found at http://www.ott.nih.gov/technology-development-coordinators

I agree to NOT receive the cell lines until my IC TDC notifies me that the MTA is complete.

_____I understand that human induced pluripotent stem cells **may not** be used for the following:

- Research in which human induced pluripotent stem cells are introduced into non-human primate blastocysts.
- Research involving the breeding of animals where the introduction of human induced pluripotent stem cells may contribute to the germ line.

Guidance for the policy on use of human iPS cells by NIH intramural researchers can be found at https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/use-human-stem-cells

Signatures

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Human Induced Pluripotent Stem Cells (iPSCs)

Investigator:_____	_____
Printed Name, Lab, IC:	Date
Lab Chief: _____	_____
Printed Name	Date

Forward a copy of the completed, approved registration form to Melissa Colbert

colbertmc@od.nih.gov

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